FLIR SYSTEMS

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Docket Management Branch (HFA-305)
Food and Drug Administration, Rm 1-23
12420 Parklawn Drive
Rockville, MD 20857

June 14, 2000

Dear Sir:

Re: Variance Amendment Application per 21 CFR 1010.4b

FLIR System, Boston has obtained a variance (99V-4065, expiry date Dec. 17, 2004) for the use of a laser range finder, model number ELRF-2M, manufactured by Advance Laser Systems Technology Inc. of Orlando, Florida, in FLIR System's MK III/MARFLIR product family (FDA Access Number 9811735). However the variance was granted for sales to US government or its agencies only. We intend to market a variation of the MK III/MARFLIR family for commercial application, using the identical laser range finder. This is a request for a variance to the performance standard and allows sales to non-US government entities.

The rationale for this request for amendment is attached herein.

Should you need further information, please contact the undersigned:

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Kin Wong
Quality Assurance Manager

Attachment – Two extra copies

99V-4065

AMD1

Application for Variance Amendment
Information Required per 21 CFR 1010.4b

1. **The variance number and expiration date:** 99V-4065, expiry date Dec. 17, 2004

2. **The amendment or extension requested and basis for the amendment or extension.** The amendment requested here is to allow the sales of the same laser model for commercial market. The basis for the request is that there is no difference in the application between the US government and the commercial application. FDA requires the radiant energy to be measured using a 50 mm aperture. This results in a typical radiant energy of 10 milli Joules @ for a 20ns pulse at 1536 nm. FDA standard for Class I laser product is 7.9 milli Joules maximum. The rationale for the FDA standard is that because the beam diameter is larger than the eye's pupil, only a small (safe level) of energy could enter the naked eye; however a pair of binoculars could collect all the energy and funnel it into the eye. This rationale negates the fact binoculars have poor optical transmission at the IR wavelength of the laser, and the energy reaching the eye would be at a safe level. Under the ANSI scenario, the energy should be measured using a 7 mm aperture. In addition, 21 CFR 1040.10(e)(3)(i) allows the use of a 7 mm aperture for measurement in a locale where the emitted laser radiation is unlikely to be viewed with optical instruments: as is the case with which these laser rangers are used by personnel on a sea craft in a surveillance situation or search and rescue operation. It is extremely rare for the target to be aware that they are under surveillance by the infrared camera with the laser range finder or difficult for the target to see the search and rescue sea craft is approaching in total darkness (infra-red camera is used for night vision). The proposed deviation here is to follow ANSI's standard for Class I device measurement. Using this measuring method, the laser range finder would easily pass FDA's Class I requirement for energy output.
3. **A description of the effect of the amendment or extension on protection from radiation produced by the product.** There is no effect on protection from radiation produced by the product.
4. **An explanation of how alternate or suitable means of protection will be provided.** Not applicable.

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